

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : BERTHET, Francois-Xavier Jacques *et al.*
Serial No. : 10/523,114
Filing Date : August 2, 2005
Title : *Vaccine Composition Comprising Transferrin Binding
Protein and Hsf from Gram Negative Bacteria*
Group / Art Unit : 1645
Examiner : ARCHIE, Nina
Confirmation No. : 4557
Docket No. : B45314

MAIL STOP AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW – REMARKS

Sir:

Pending claims 1-8, 13-19, 45-47, and 51-55 stand provisionally rejected on the grounds of nonstatutory obviousness-type double patenting over claims 3, 4, 11, 17, 20, 22, 50-52, 54-61, 95, 96, 98, and 114-132 of co-pending US Patent Application No. 10/523,117. In addition, claims 1-8, 13-19, 45-47, and 51-55 stand rejected under 35 U.S.C. §102(b) as anticipated by WO2001/009350 (Berthet *et al.*). These remarks are filed in response to the current Final Office Action mailed October 6, 2010. Also filed herewith are a Notice of Appeal and a Request for Pre-Appeal Brief Review. Applicants respectfully request review by a Pre-Appeal Panel in light of the following remarks.

The rejection of claims 1-8, 13-19, 45-47, and 51-55 for double-patenting is provisional as the cited patent application has not yet been deemed allowable. Accordingly, the present remarks are directed solely to the rejection of the claims under 35 U.S.C. §102(b).

Claim 1 (from which all the other pending claims depend) is directed to an immunogenic composition comprising an isolated transferrin binding protein (Tbp) or antigenic fragment thereof and an isolated Hsf like protein or antigenic fragment thereof from the same or different Gram negative bacteria.

Berthet *et al.* teach a bleb preparation having one or more upregulated genes, where the genes are selected from a list of 21 antigens. The antigen list includes Hsf-like, TbpA, and Tbp. Thus, the reference discloses a genus of many possible antigen combinations containing varying numbers of distinct antigens, including 210 possible combinations of two different antigens. However, this reference does not teach the specific combination of an Hsf-like antigen and a Tbp antigen. In contrast, all of the immunogenic compositions encompassed by the present claims comprise this specific antigen combination.

According to the Federal Circuit, lists and genera should be treated differently when determining whether a reference is anticipatory. For example, in *Atofina v. Great Lakes Chem Corp.*, the Federal Circuit stated, “[i]t is well established that the disclosure of a genus in the prior art is not necessarily a disclosure of every species that is a member of that genus.” *Atofina v. Great Lakes Chem Corp.* 441 F.3d 991, 992 (Fed. Cir. 2006). In the present case, the Berthet *et al.* reference *generically* teaches a large number of possible antigen combinations but does not list the *specific* combination of an isolated transferrin binding protein (Tbp) or antigenic fragment thereof and an isolated Hsf like protein or antigenic fragment thereof from the same or different Gram negative bacteria. Accordingly, under the holding of *Atofina*, this reference does not anticipate the subject matter of claim 1 or dependent claims 2-8, 13-19, 45-47, and 51-55. It is the specificity and particularity of the antigen combination recited in the present claims that distinguish it from the compositions taught by Berthet *et al.*

The Examiner states that the Applicants’ arguments are not sufficient to overcome the rejection under 35 U.S.C. §102(b) because the rejected claims recite open language and thus encompass immunogenic compositions having components in addition to an isolated Tbp or antigenic fragment thereof and an isolated Hsf like protein or antigenic fragment thereof. The Applicants agree that the present claims encompass such combinations. However, even when construed to encompass additional components, the immunogenic compositions of claim 1 and its dependent claims are not anticipated by Berthet *et al.* because the reference fails to teach the combination of an Hsf-like antigen and a TbpA or TbpB antigen with sufficient specificity to anticipate the claimed subject matter. Accordingly, the cited art does not teach every limitation of the rejected claims.

In conclusion, the Final Office Action fails to provide all the elements required for a *prima facie* showing that claims 1-8, 13-19, 45-47, and 51-55 are anticipated because the Examiner has not demonstrated that Berthet *et al.* specifically teach all the limitations recited in these claims. Accordingly, the rejection of the pending claims under 35 U.S.C. §102(b) should be withdrawn. Applicants request that the Panel grant this relief.

Respectfully submitted,

/Kathryn L. Coulter/

Kathryn L. Coulter
Attorney for Applicant
Reg. No. 45,889

Date: 1/6/2011
Customer No. 23347
GlaxoSmithKline
Global Patents
Five Moore Drive, P.O. Box 13398
Research Triangle Park, NC 27709-3398
Telephone: (919) 483-1467
Facsimile: (919) 483-7988